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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,304	09/05/2003	Andrea M. McPhillips	02972938	8208

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EXAMINER
CLAYTOR, DEIRDRE RENEE

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
09/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/656,304	MCPHILLIPS ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/30/2007 has been entered.

Response to Arguments

Applicant's response and amendments to claim 1 filed on 7/30/2007 are hereby acknowledged. Applicant's amendments to claim 1 are sufficient to overcome the 35 U.S.C. 112, second paragraph rejection.

Applicants address the Objection to the Drawings by replacing Figure 4. However, the Office Action mailed on 1/29/2007 noted that there were multiple discrepancies between the description of the drawings of the specification and the label of the drawing disclosed. The Examiner pointed out Figure 4 strictly as an example; it was not meant to limit the Objection to Figure 4 alone. It is suggested to compare the figures and the labels of the axes of the figures with what is written in the specification to verify that the figures match up. The Objection to the Drawings is maintained.

Applicants incorporate all of the arguments from the response to the June 15, 2006 Office Action (December 15, 2006). The argument given is that the combined references for the 35 USC 103 rejections do not teach or suggest that a single dose of

the composition achieves a Tmax at least within 0.041 hour. At the time the issue was considered new matter and the present amendments of 7/30/2007 are sufficient to overcome this issue. However, it was addressed in the Final Action that it would be obvious to a person of skill in the art to vary the mean mass median aerodynamic diameter provided in the composition to attain the desired Tmax.

Due to Applicant's amendments, the following modified rejections are being given below.

Claim Rejections – 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 rejected under 35 U.S.C. 103(a) as being unpatentable over Touitou (U.S. Patent # 5,716,638) in view of Peart et al. (U.S. Patent # 6,509,005) and Vachon et al. (XP-000965573).

Touitou teaches a medical composition comprising ethanol (49%), water (29.4%), and propylene glycol (19.6%) in combination with tetrahydrocannabinol (THC; 7 μci/ml) as the active agent (see Table I), which encompasses claims 1-8.

Touitou fails to teach the dosage form of THC and an aerosol form of the composition.

Peart et al. teach a stable aerosol-dispensable pharmaceutical composition comprising a pharmaceutically effective concentration of delta-9-THC (Column 1, lines 20-27; claims), which is absorbed within seconds and delivered to the brain efficiently. Peart et al. also teach that an organic solvent such as ethanol can assist in solubilizing the delta-9-THC (Column 5, lines 50-52; claims). It is further taught that the optimal size of the respirable dose, or the mass of delta-9-THC in particles with aerodynamic diameters small enough to be delivered to and absorbed by the lungs, is less than 10 μm in size (Column 6, lines 37-48), allowing for effective inhalation. A metered dose inhaler (MDI) is also taught for the aerosol administration of delta-9-THC.

Vachon et al. teach propylene glycol and water (in a ratio of 9:1) as a vehicle for holding THC (4.5 g/100ml) to be administered as an inhaled aerosol with a nebulizer (Materials, Methods and Subjects).

Furthermore, it is obvious to vary and/or optimize the mean mass median aerodynamic diameter provided in the composition, according to the guidance provided by Peart et al., to provide a composition having the desired properties such as the desired T_{max}. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Accordingly, it would have been obvious to one skilled in the art at the time the invention was made to combine the teachings of Touitou and Peart and form a stable aerosolable composition with a pharmaceutically effective amount of delta-9-THC because Touitou teaches a composition comprised of ethanol, water, and propylene

glycol with delta-9-THC as the active ingredient and Peart teaches an aerosolable composition with a pharmaceutically effective amount of THC. Further it would have been obvious to one skilled in the art at the time the invention was made to further combine the teachings of Vachon who teaches that a vehicle of propylene glycol and water in a ratio of 9:1 is capable of holding up to 4.5 g of THC/100 ml in clear solution, with Touitou and Peart, because both teach THC as a therapeutic agent and a solvent comprising ethanol. To further address the limitation of a Tmax for delta-9-THC being achieved between 0.032 hour to about 0.041 hour, and in addressing the limitation of the Tmax for 11-OH-delta-9 tetrahydrocannabinol being achieved between about 0.115 hour to about 0.208 hour, both in claim 1, the Tmax for delta-9-THC and the Tmax for its metabolite 11-OH-delta-9 tetrahydrocannabinol would obviously be the same considering that the prior art teaches the same combination and the same mean mass median aerodynamic diameter.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the composition of Touitou in an aerosolable form of Peart et al. and Vachon et al., for more rapid onset of pharmacological action in the brain after administration of delta-9 THC. One having ordinary skill in the art at the time the invention was made would have been further motivated to employ the composition of Touitou in an aerosolable form of Peart et al. with delta-9 THC particles with aerodynamic diameters less than 10 μm in size to allow for more effective inhalation and absorption by the lungs.

Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Touitou (U.S. Patent # 5,716,638) in view of Peart et al. (U.S. Patent # 6,509,005) and Vachon et al. (XP-000965573) as applied to claims 1-8 above and further in view of LaMastro (U.S. Patent # 5,258,336).

Touitou, Peart et al., and Vachon et al. references are discussed above. Peart teaches administration of a composition via a metered dose inhaler (MDI) and Vachon teaches administration via a nebulizer.

Touitou, Peart et al., and Vachon et al. do not teach a sterile and/or preserved sealed unit-or multi-unit dosage form of delta-9 THC with Type I Amber Glass.

LaMastro et al. teach a Type I amber glass composition that provides a high degree of chemical stability and protection from ultraviolet light for certain pharmaceutical compositions (Column 1, lines 10-13).

Accordingly, it would have been obvious to one skilled in the art at the time the invention was made to combine the teachings of Touitou, Peart, and Vachon in further view of LaMastro to house the composition in a sterile and/or preserved sealed unit-or multi-unit dosage form of delta-9 THC in Type I amber glass. One having ordinary skill in the art at the time the invention was made would have been motivated to use Type I amber glass because it provides chemical stability and protection from ultraviolet light for pharmaceutical compositions.

Conclusion

No claims are allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SHENGJUN WANG
PRIMARY EXAMINER

Renee Claytor